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- of a mobile phase passing through said re-useable chromatography column packing of the at least second use,
- b) determining the parameters of a function of formula I by fitting the experimental data of the inert change of the physicochemical parameter of the at least second use,
- c) determining the difference between the experimental data of the inert change of the physicochemical parameter of the at least second use and the function of formula I with the parameters determined in step b),
- d) calculating the difference between the maximum value and the minimum value of the difference determined in step c) and normalizing said difference,
- e) determining reduced separation efficacy of said re-useable chromatography column packing when the absolute value of the difference calculated in step d) is more than 0.1.

wherein the function of formula I is

$$yI = \frac{1}{2}P1 \cdot \left(1 + \operatorname{erf}\left(\frac{x - m}{s \cdot \sqrt{2}}\right)\right) + A0,$$

with the amplitude P1, the starting value A0, the mean value m, the standard deviation s, and with

$$\operatorname{erf}(x) = \frac{2}{\sqrt{\pi}} \sum_{0}^{\infty} \frac{(-1)^{n} x^{2n+1}}{(2n+1)n!}.$$

- 2. The method according to claim 1, wherein said inert change is recorded during the purification by a standard conductivity measuring device.
- **3**. The method according to claim **1** wherein said inert change is recorded during the purification by a standard adsorption measuring device.
- 4. The method according to claim 1, wherein said inert change of at least one physicochemical parameter of a mobile phase passing through said re-useable chromatography column packing is a change effected by the change of the concentration of a substance in the mobile phase that does not interact with the re-useable column packing.
- **5**. The method according to claim **1**, wherein said inert change is a change in conductivity, as measured by a standard conductivity measuring device.
- 6. The method according to claim 1, wherein said inert change of at least one physicochemical parameter of a mobile phase passing through said re-useable chromatography column packing is a change of from 100% of a solution containing a denaturing agent to 100% of a solution not containing said denaturing agent, or vice versa.
- 7. The method according to claim **6**, wherein said denaturing agent is selected from sodium hydroxide, guanidinium chloride, urea or organic solvent.
- **8**. The method according to claim **1**, wherein said inert change is a sigmoid change.
- 9. The method according to claim 1, wherein said inert change is a change over time.
- 10. A method for the chromatographic purification of a polypeptide, wherein at least one chromatography step using a re-useable chromatography column packing is contained, wherein said method comprises the following steps:
  - a) identifying and determining the experimental data of an inert change of at least one physicochemical parameter

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of a mobile phase passing through said re-useable chromatography column packing of the at least second use,

- b) determining the parameters of a function of formula I by fitting the experimental data of the inert change of the physicochemical parameter of the at least second use,
- c) determining the difference between the experimental data of the inert change of the physicochemical parameter of the at least second use and the function of formula I with the parameters determined in step b),
- d) calculating the difference between the maximum value and the minimum value of the difference determined in step c) and normalizing said difference,

wherein the function of formula I is

$$yI = \frac{1}{2}P1 \cdot \left(1 + \operatorname{erf}\left(\frac{x - m}{s \cdot \sqrt{2}}\right)\right) + A0,$$

with the amplitude P1, the starting value A0, the mean value m, the standard deviation s, and with

$$\operatorname{erf}(x) = \frac{2}{\sqrt{\pi}} \sum_{n=0}^{\infty} \frac{(-1)^n x^{2n+1}}{(2n+1)n!},$$

and

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further using the re-useable chromatography column packing when the absolute value of the difference calculated in step d) is 0.05 or less, or

performing an additional characterization and/or assessment of the purified polypeptide when the absolute value of the difference calculated in step d) is more than 0.05 but less than 0.2, or

changing the re-useable chromatography column packing when the absolute value of the difference calculated in step d) is 0.2 or more.

- 11. The method according to claim 10, wherein said inert change is recorded during the purification by a standard conductivity measuring device.
- 12. The method according to claim 10, wherein said inert change is recorded during the purification by a standard adsorption measuring device.
- 13. The method according to claim 10, wherein said inert change of at least one physicochemical parameter of a mobile phase passing through said re-useable chromatography column packing is a change effected by the change of the concentration of a substance in the mobile phase that does not interact with the re-useable column packing.
- 14. The method according to claim 10, wherein said inert change is a change in conductivity, as measured by a standard conductivity measuring device.
- 15. The method according to claim 10, wherein said inert change of at least one physicochemical parameter of a mobile phase passing through said re-useable chromatography column packing is a change of from 100% of a solution containing a denaturing agent to 100% of a solution not containing said denaturing agent, or vice versa.
- 16. The method according to claim 15, wherein said denaturing agent is selected from sodium hydroxide, guanidinium chloride, urea or organic solvent.
- 17. The method according to claim 10, wherein said inert change is a sigmoid change.
- 18. The method according to claim 10, wherein said inert change is a change over time.

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